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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,563	11/25/2003	Tal Kafri	9435-2	5850

7590 11/22/2006

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EXAMINER

BURKHART, MICHAEL D

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 11/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

**Application No.**

10/721,563

**Applicant(s)**

KAFRI ET AL.

**Examiner**

Michael D. Burkhart

**Art Unit**

1633

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 31 October 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See continuation sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: 5-8, 12-15 and 19-23.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 9, 10, 16, 17 and 24-29.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered, because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See continuation sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
13. ☐ Other: \_\_\_\_\_.

Art Unit: 1633

**Continuation Sheet**

3 (a). Claims 10 and 17 have been amended to depend from claims 5 and 13, respectively.

Claims 10 and 17 both recite the limitation "the portion of the U3 region has been that has been deleted." There is insufficient antecedent basis for this limitation in the claims. Furthermore, the proposed amendment raises USC 112 2nd ¶ issues regarding what is deleted from the U3, is the *loxP* site recited as being in the U3 (in claims 5 and 13) retained, or is deleted?

Claim 20, which depends from claim 5, has been amended to recite a method of making "a single-LTR circular HIV-1 form plasmid." There is no mention of HIV-1 in claim 5, and using the vector of claim 5 in the method of claim 20 will not necessarily result in an HIV-1 plasmid. This is because claim 5 encompasses other retroviral vectors not based on HIV-1 (e.g. MuLV), and using such vectors in the claimed method will not result in an HIV-1 plasmid.

Applicants assert that the claim was previously amended, as suggested by the Examiner in a telephone conference, in order to put the claim in condition for allowance. This is incorrect. The telephone conference was a courtesy to indicate, since claim 5 was considered allowable, that any reply to the Notice of Non-Compliant Amendment dated 4/6/2006, should address this issue with claim 20, and thus further prosecution of the application. It is applicant's responsibility to draft any such amendments in accordance with the instant disclosure.

11. Applicants assert that the subject matter of claim 9, currently rejected under 35 USC 112 1st ¶ as New Matter, is supported by the example of pTK589. The instant claim recite a broad genus of potential nucleic acids having retroviral nucleic acid components such as an LTR, packaging

Art Unit: 1633

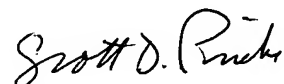
signal, rev responsive element, polypurine tract, and primer binding site, from any retrovirus. Furthermore, the claim broadly recites bacterial nucleic acid components, such as an origin of replication and selection marker, and any eukaryotic promoter. The pTK589 vector provides support for a single species of the broadly claimed genus of nucleic acids, wherein the retroviral components are all from HIV-1, the eukaryotic promoter is the CMV promoter, and the bacterial components are a pUC origin of replication and ampicillin resistance. This single species does not provide support for the broadly claimed genus of nucleic acids, and as indicated previously, the remainder of the specification provides no support for the genus.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhardt whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael D. Burkhardt  
Examiner  
Art Unit 1633



**SCOTT D. PRIEBE, PH.D**  
**PRIMARY EXAMINER**